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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,559	11/12/2003	Daniel J. Smith	GYN5013	6912
27777	7590	09/21/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			SONNETT, KATHLEEN C	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/706,559

Applicant(s)

SMITH ET AL.

Examiner

Kathleen Sonnett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-22 is/are allowed.
- 6) ☒ Claim(s) 1, 7-12, 14, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 2-6, 13 and 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/15/04, 6/10/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 11 is objected to because of the following informalities: omitted word. The word "one" should follow "at least" in line 1 of claim 11. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, 9-10, 14, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Rocheleau et al. (U.S. 6,641,525). Rocheleau et al. discloses a surgical assembly comprising a surgical passer (60, 58) having a wire portion (col. 5 ll. 57-58) attached to a handle (64), the wire portion having a free distal end, an outer periphery, and at least one recess (see fig. 11) therein in a distal end region. The surgical assembly further includes a tube element (54) having a proximal end, a tissue penetrating distal end (fig. 17), and a channel extending therein from an opening at the proximal end and defined by an inner periphery, the channel having at least one projection (98; fig. 6) projecting outwardly into the channel in a distal end region thereof, wherein the outer periphery of the surgical passer is dimensioned relative to the inner periphery of the channel of the tube element so that the surgical passer is positionable within the tube element, and wherein, when so positioned, the at least one tube element projection engages the at least one surgical passer recess to removably couple the surgical passer to the tube element (col. 11 ll. 52-62).

Regarding claim 14, Rocheleau et al. discloses a surgical passer having a wire portion coupled to a handle, at least a portion of the wire portion having a curved contour, a free distal end, an outer periphery, and having at least one recess therein in a distal end region; a tube element having a proximal end coupled to the tape to be implanted (fig. 17), a tissue penetrating distal end, and a channel extending therein from an opening at the proximal end, the channel having an inner periphery and having at least one projection projecting outwardly into the channel in a distal end region thereof, the tube element having a configuration such that it can be removably positioned over the distal end of the surgical passer and having a contour that substantially follows the contour of the surgical passer; wherein when the tube element is removably positioned over the distal end of the surgical passer, the at least one projection on the surgical passer engages the at least one recess in the tube element as discussed above. Regarding the curved contour, the surgical passer is cylindrical and therefore has a curved contour which the tube element follows since it is has a cylindrical channel that holds the surgical passer.

Regarding claim 7, see fig. 10 and table A. S has a length of 0.06 inches, which is approximately 1.524 mm. Therefore the radius would be 0.762 mm.

Regarding 9, see fig. 10 and table A. P has a length of 0.25 inches, which is approximately 6.35 mm.

Regarding claims 10 and 18, the at least one recess is a single recess extending around a circumference of the surgical passer (see fig. 11). The at least one projection is a mating shoulder that fits into this recess. It is shown in cross section in fig. 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rocheleau et al. (U.S. 6,641,525). Rocheleau et al. discloses the invention substantially as stated above, but fails to disclose a chamfered leading edge on the surgical passer. Instead, Rocheleau et al. discloses a tapered leading edge on the surgical passer. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a chamfered leading edge on the surgical passer because Applicant has not disclosed that the chamfered edge provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Rocheleau et al.'s device, and applicant's invention, to perform equally well with either a tapered leading edge on the surgical passer as taught by Rocheleau et al. or the claimed chamfered edge because both would perform the same function of coupling the surgical passer to the tube element. Therefore, it would have been prima facie obvious to modify Rocheleau et al. to obtain the invention as specified in claim 8 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Rocheleau et al.

Claims 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocheleau et al. (U.S. 6,641,525). Rocheleau et al. discloses the surgical assembly of claims 1 and 14 as discussed above including at least one recess on the surgical passer and at least one projection on the tube element. Rocheleau et al. fails to disclose that the at least one projection

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is a plurality of projections spaced apart about the diameter of the channel. However, Rocheleau et al. does disclose that a variety of mating structures can be employed including bumps, grooves, and slots (col. 11 ll. 63-67). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a plurality of projections instead of the single mating shoulder because Applicant has not disclosed that a plurality of projections provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Rocheleau et al.'s device, and applicant's invention, to perform equally well with either a single mating shoulder as taught by Rocheleau et al. or the claimed plurality of projections because both would perform the same function of coupling the surgical passer to the tube element. Therefore, it would have been prima facie obvious to modify Rocheleau et al. to obtain the invention as specified in claims 11 and 19 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Rocheleau et al.

Claims 1, 7-8, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (U.S. 6,024,690) in view of Ciezki et al. (U.S. 6,725,081). Lee et al. discloses a surgical assembly comprising a surgical passer having a wire portion (44), the wire portion having a free distal end, an outer periphery, and at least one recess (61) therein in a distal end region. The surgical assembly further includes a tube element (60) having a proximal end, a tissue penetrating distal end, and a channel extending therein from an opening at the proximal end and defined by an inner periphery, the channel having at least one projection (62) projecting outwardly into the channel in a distal end region thereof, wherein the outer periphery of the surgical passer is dimensioned relative to the inner periphery of the channel of the tube element so that the surgical passer is positionable within the tube element, and wherein, when so

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positioned, the at least one tube element projection engages the at least one surgical passer recess to removably couple the surgical passer to the tube element (see fig. 7).

Regarding claim 7, the surgical passer can have a radius of 1.5 mm (col. 5 ll. 65-67).

Regarding claim 10, see fig. 7 and col. 7 ll. 46-48.

Regarding claim 12, the surgical passer (44) is cylindrical and its outer surface represents a contour. The tube element (60) fits around the suture passer and is therefore configured to follow the contour of the passer.

Lee et al. fails to disclose that the surgical passer is coupled to a handle.

However, Ciezki et al. discloses that it is old and well known to include a handle coupled to a device used to deliver radiation to a treatment site within a vessel. Ciezki et al. discloses that the handle aids in manipulating the device through the body (col. 7 ll. 30-32). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Lee et al. to include a handle coupled to the surgical passer as made obvious by Ciezki et al. in order to facilitate the manipulation of the device through a patient's body.

Regarding claims 8 and 11, modified Lee et al. does not expressly disclose that the leading edge of the surgical passer is chamfered, only that it may be hemispherical if desired. In regards to claim 11, Lee et al. does not disclose that the at least one projection is a plurality of projections spaced apart about the diameter of the channel. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a chamfered leading edge on the surgical passer or a plurality of projections instead of the single projection (62) because Applicant has not disclosed that the chamfered edge or a plurality of projections provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Lee et al.'s device, and applicant's invention, to perform equally well with either a single projection or hemispherical

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leading edge as taught by Lee et al. or the claimed chamfered edge (claim 8) and plurality of projections (claim 11) because both would perform the same function of coupling the surgical passer to the tube element. Therefore, it would have been prima facie obvious to modify Lee et al. to obtain the invention as specified in either claim 8 or claim 11 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Lee et al.

Allowable Subject Matter

Claims 20-22 are allowed.

Claims 2-6, 13, and 15-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
9/12/2006


GLENN K. DAWSON
PRIMARY EXAMINER